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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.     | CONFIRMATION NO. |
|--|-------------|----------------------|-------------------------|------------------|
| 09/817,748   | 03/26/2001  | Steven M. Tracy      | UNMC -0027              | 7857             |
| 7590 12/19/2003<br>Janet E. Reed, Esq.<br>Woodcock Washburn LLP<br>46th Floor<br>One Liberty Place<br>Philadelphia, PA 19103 |             |                      | EXAMINER<br>GUZO, DAVID |                  |
|  |             |                      | ART UNIT<br>1636        | PAPER NUMBER     |
| DATE MAILED: 12/19/2003  |             |                      |                         |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/817,748

Applicant(s)

TRACY, STEVEN M.

Examiner

David Guzo

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 16-24,30 and 31 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 16-24,30 and 31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_ 6) ☐ Other: \_\_\_\_

### Detailed Action

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/10/03 has been entered.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 16-24 and 30 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 5, 7-8, and 12-18 of U.S. Patent No. 6,071,742. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims recite viral vectors comprising attenuated CBV vectors which can express an immunomodulatory gene. The first independent claim in the instant application recites an attenuated CBV

vector which expresses an immunomodulatory protein which induces a shift from a Th1 to a Th2 immune response. Applicants note in the instant specification that immunomodulatory proteins that can induce such as response include IL-4 and IL-10. The claims in the '742 patent claim CBV vectors comprising the same sequences encoding IL-4 or IL-10. The instant claims read on any CBV genome modified to encode an attenuated CBV while the claims in the '742 patent read on CBV3 genomes; however, the broad instant claims encompass the CBV3 vectors recited in the '742 patent. The claims in the '742 patent would anticipate the claimed invention.

Claims 16-24 and 30-31 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-19, 22 and 25-30 of U.S. Patent No. 6,323,024. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims recite attenuated CBV genomes which encode and express cytokines such as IL-4 and IL-10. The claims in the '024 patent recite CBV vectors with the same characteristics, i.e. the CBV can be a CBV3 genome, the same nucleotide substitutions at positions 233, 234 and 236, the same changes to the 5' untranslated region of the virus, cloning sites at the same positions in the genome, etc. While some claims in the '024 patent read on CBV expression of any heterologous gene, other claims recite expression of any cytokine and claim 30 in the '024 patent specifically recites expression of IL-4 or IL-10.

Claims 16-24 and 30 are directed to an invention not patentably distinct from claims 1-3, 5, 7-8 and 12-18 of commonly assigned U.S. Patent 6,071,742 and claims 16-24 and 30-31 are directed to an invention not patentably distinct from claims 1-19, 22 and 25-30 of commonly assigned U.S. Patent 6,323,024. Specifically, the instant claims are not patentably distinct for the reasons cited in the above obviousness-type double patenting rejections.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302). Commonly assigned U.S. Patents 6,071,742 and 6,323,024, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee is required under 35 U.S.C. 103(c) and 37 CFR 1.78(c) to either show that the conflicting inventions were commonly owned at the time the invention in this application was made or to name the prior inventor of the conflicting subject matter. Failure to comply with this requirement will result in a holding of abandonment of the application.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 21-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 21 (and dependent claim 22) is vague because there is no antecedent basis for the term "the transcription regulatory region" in the claims from which it depends.

Applicants' arguments directed against the 35 USC 112, 1<sup>st</sup> paragraph rejection made in the previous Office Action are moot in view of the amendments to the claims wherein method claims were cancelled and the composition claims amended to delete any reference to therapeutic compositions. The claims read on CBV vectors which express immunomodulatory proteins such as IL-4.


No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo, Ph.D., whose telephone number is (703) 308-1906. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. After January 14, 2003, the examiner can be reached at (571) 272-0767. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D., can be reached on (703) 305-1998. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

David Guzo  
December 14, 2003

  
DAVID GUZO  
PRIMARY EXAMINER